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January 15, 1996

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Approved by

Laboratory Procedures

A. G. King, Manager Hanford Analytical Services

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1.0 PURPOSE

This section implements the requirements of WHC-CM-3-5, <u>Document Control and Records</u>
<u>Management Manual</u>, Section 12.5, "Technical Procedure Standard, as applied to Analytical Services'
(AS) laboratory technical procedures. The AS laboratory procedure process is administrated by the Procedures Administration (PA) function of AS Documentation Administration.

2.0 SCOPE

This section applies to all elements involved in processing laboratory technical procedures. It does not apply to non-technical procedures, administrative desk instructions, or work packages controlled under WHC-CM-1-8, Work Management Manual.

A technical procedure dictates a function (a sequence of actions) to be performed to achieve a defined outcome. Procedures are developed to safely perform work activities that directly affect the operating or design configuration, operability or accuracy of laboratory facilities, systems, equipment or components. See Section 1.1 of this manual for the AS policy regarding safety priority and procedure compliance. For the purposes of this section, the terms "technical procedure, "laboratory procedure," and "procedure" are synonymous.

Deviations from the requirements of this section are documented and approved by waiver as identified in WHC-CM-1-3, <u>Management Requirements and Procedures</u>, MRP 2.21, "Controlled Manual Waiver Process."

2.1 Implementation

- 1. Existing technical procedures are brought into compliance with this standard as they are revised.
- 2. New technical procedures are developed in compliance with this standard.

3.0 DEFINITIONS

Approval Designator

The system which establishes approval requirements based on a document's importance to Safety, Environment and Quality. The Approval Designators are assigned by the technical authority per the criteria given in WHC-CM-3-5, Section 12.7, "Approval of Environmental, Safety, and Quality Affecting Documents," and WHC-CM-7-5, Section 13, "Environmental Compliance Officers, Central Environmental Committee, Environmental Reviews."

Approval Authority

The technical authority's cognizant manager or designee thereof. Approval authorities are delegated to sign those procedures within their field of expertise. The 222-S Analytical Operations Manager is the designated approval authority for all 222-S laboratory operating (LO) procedures.

Approved Technical Procedure

A laboratory technical procedure approved, at a minimum, by the required AS organizations and in accordance with the assigned Approval Designator. Approval can be in written form, by signature or initials, by documented telephone conversation (telecon), or sent electronically via cc:mail.

Controlled Copy

A hard copy or electronic version of an approved laboratory technical procedure that is maintained at specific controlled user locations, normally in controlled notebooks. Goldenrods (performance copies), verified white copies, and procedure change authorizations (PCAs) are considered controlled copies and are identified as such.

Goldenrod (Performance Copy). A copy of an approved technical procedure that is released by PA, placed in specific controlled user locations, and validated to be the most recent revision. Each copy is identified as being valid by a triangular release stamp and assigned controlled notebook number on page 1, and by being issued on goldenrod paper.

<u>White Copy</u>. A copy of a an approved technical procedure used for reference purposes or to record one-time performance of an activity. White copies are available electronically on the Lab Procedure network directory or in hard copy from Procedures Administration.

History File

A file containing documentation related to the evolution of a procedure. The file contains such items as records of changes, and review comments and their disposition.

Inactive (Hold) Procedure

A laboratory technical procedure temporarily not required by the laboratory and placed in hold status.

Modification

An alteration to a technical procedure that does not change the procedure's intent, quality, safety, or process.

Periodic Review

The periodic function of verifying and validating that a technical procedure meets and reflects all current applicable technical, administrative, and facility configuration changes that have been made since the last revision.

Procedure Change

An approved change from one word to less than the entire procedure. A change is classified as a revision, modification, or procedure change authorization, and may be permanent or temporary.

Procedure Change Authorization (PCA)

The AS-specific designated form that authorizes immediate implementation of approved changes to an existing technical procedure. PCAs are valid for a 90-day period of time or duration of an event. They are issued on pink paper and considered controlled documents. The mostcurrent PCA form is available from PA or on the Lab Procedures network directory. See Attachment 1 for an example.

Procedure Review and Approval Form (PRAF)

The AS-specific designated form for process, review, and approval of laboratory technical procedures. The PRAF documents such activities as requests for changes, inactivations, voids, reactivations, periodic reviews, and technical review comments. The most current PRAF is available from PA or electronically on the Lab Procedure network directory. See Attachments 2 and 3 for example forms.

Review

The portion of the laboratory technical procedure development process that includes crossdisciplinary review, verification, validation, and disposition of resulting valid technical comments.

Validation. The portion of procedure review that tests procedure usability, correctness, and compatibility with the equipment or system. Validation is normally performed by personnel who use the procedure.

Verification. The procedure review function that independently evaluates the procedure for technical accuracy and proper format. Verification includes cross-disciplinary reviews requested by the technical authority and any additional organization, personnel, or other discipline to ensure the procedure is free of technical errors.

Revision

A technical change to a laboratory technical procedure that alters the results, requirements, or methods by which a procedure is performed, or that does not meet the definition of a modification, including alteration of a regulatory method (see HASQAP).

Technical Authority

Technical authorities are cognizant engineers/scientists or other facility-designated personnel with the necessary training and experience to fulfill the technical responsibilities for the procedure. Normally, a procedure writer is the technical authority assigned responsibility for the procedure, but some exceptions do exist.

222-S Laboratory Waste Stream Fact Sheet

Although not considered part of a procedure, waste stream fact sheets (WSFSs) are prepared by the technical authority in accordance with LAP-106-100, Waste Stream Fact Sheet Development and Issuance (Predesignation of Waste), to record waste stream information. WSFSs are reviewed by the Environmental Compliance Officer or designee and verified by quality assurance. Once approved, the WSFS is filed with the master copy and becomes part of the procedure history file upon being superseded. A copy of the WSFS is also filed with each performance copy of the procedure in the laboratory.

User Test (Blue User)

An unreleased laboratory technical procedure that has been approved for testing under the direction of a technical or approval authority. User test authorization is obtained on the PRAF and the user test procedure printed on blue paper for unique identification.

Void (Canceled) Procedure

A laboratory technical procedure that is no longer required by the laboratory. Void procedures are considered canceled, but can be reactivated.

ZDOX

The AS-specific designated tracking system that tracks each step of the procedure process on a real-time basis. ZDOX is controlled solely by Procedures Administration.

4.0 RESPONSIBILITIES

The following defines the <u>functional</u> roles and responsibilities of the various entities involved in the laboratory procedure function.

4.1 Manager, Analytical Services

The AS Manager, or designee, is responsible for:

- Implementing this section as the defined, disciplined laboratory procedure standard
- Setting the policy for laboratory technical procedure use and applicability
- Issuing an approval authority list that assigns authority and establishes accountability for laboratory technical procedures
- Ensuring the AS laboratory procedure standard complies with the requirements identified by WHC-CM-3-5, <u>Document Control and Records Management Manual</u>, Section 12.5, "Technical Procedure Standard"
- Determining AS specific training requirements for procedure owners, users, and developers (procedure writers, technical authorities, and reviewers)
- Ensuring personnel participating in procedure development, review, and approval are trained and qualified to do so.

4.2 Approval Authorities

Approval authorities are responsible for review of procedures in their field of expertise. A current approval authority list is available on the Lab Procedure network directory. The 222-S Analytical Operations Manager is the designated approval authority for all 222-S laboratory operating

(LO) procedures and designated reviewer of all 222-S laboratory procedures. Approval authorities are responsible for:

- Owning procedures that address the applicable requirements listed in Paragraph 5.0 of this section
- Identifying technical authorities, as appropriate
- Ensuring AS procedure users utilize and comply with procedures in accordance with this manual, Section 1.1, "Safety Priority and Procedure Compliance Policy"
- Reviewing procedures under their cognizance and in their field of expertise
- Ensuring all required personnel review and approve procedures (additional reviews/approvals can be added by the approval authority as deemed appropriate)
- Requesting or approving, via PRAF, removal of unused procedures from controlled user locations
- Providing PA with documentation indicating any delegation of their approval authority.

4.3 Manager, Documentation Administration

The AS Documentation Administration manager is responsible for:

- Maintaining a controlled procedure function meeting the requirements identified in this section
- Ensuring procedure processing is complete and procedures are issued in a timely manner and in accordance with this standard
- Ensuring procedures are available when needed.

4.4 Procedures Administration

Procedures Administration personnel process laboratory technical procedures, incorporate required changes, prepare the final document, perform the final administrative review, and sign as the accountable Procedure Administrator. The following are also the responsibilities of Procedure Administration personnel.

- Assisting in the assignment of an identification number to procedures, with concurrence of the technical authority for all new procedures (see Appendix B for analytical procedure numbering).
- Ensuring all resolved comments are incorporated.

- Releasing completed procedures by applying a release stamp and date of release to page one of each procedure.
- Issuing controlled copies, printed on goldenrod paper, of each procedure.
- Distributing and maintaining availability of laboratory technical procedures.
- Keeping the Lab Procedure network directory current.
- Removing procedures from controlled notebooks, as applicable and/or requested.
- Ensuring procedures are processed, reviewed, and approved in a timely manner according to this standard.
- Maintaining the ZDOX and MAINTRAK Laboratory Procedure Tracking Systems, databases for tracking procedure status, current.
- Keeping the Analytical Services Laboratory Procedures index current via Soft Reporting.
- Ensuring the maintenance procedure index available on the Lab Procedure network directory is current.
- Tracking periodic reviews and processing procedures within the periodic review cycle.
- Generating and maintaining a keyword index to minimize redundancy.
- Tracking user test (blue user) procedures.
- Assigning numbers to, processing, and tracking PCAs.
- Maintaining a procedure history file in the Laboratory Technical Information Center.

4.5 Technical Authorities

Normally, AS technical authorities act as procedure writers; however, there are some exceptions. Technical authorities are ultimately responsible for submitting to PA a procedure containing all the required elements and ensuring that a procedure is technically adequate, accurate, and consistent. The following statements explain how technical authorities accomplish this.

- They meet the training and qualification requirements established by the Manager, Analytical Services.
- They provide technical direction for AS procedure writers, as applicable.

- They determine, with approval authority concurrence, the need for placing any unneeded procedure in inactive, void, or reactivate status.
- They specify or confirm goldenrod locations.
- Before preparing a new procedure, they verify there are no existing procedures
 that could be used with minor changes to minimize redundancy and promote
 standardization and consistency of procedures.
- They provide appropriate keywords for each assigned procedure.
- They assign the identification number for new procedures with the assistance of PA.
- They designate a procedure change as a revision or modification.
- They provide a documented basis for each procedure change.
- They identify training needs for each procedure change or new procedure.
- They identify actions for procedure compatibility to lab equipment or system configuration.
- They prepare, change, and perform the periodic review of assigned procedures.
- They determine appropriate level of detail required based on the training and qualification of the final user.
- They assign approval designators for each procedure, in accordance with WHC-CM-3-5, Section 12.7.
- They conduct procedure verification.
- They designate any additional procedure reviewers to verify adequacy, accuracy, and consistency of the procedure.
- They ensure performance of Unreviewed Safety Question screens and evaluations as necessary to ensure safety basis is not affected by the procedure.
- They ensure the procedure complies with the facility safety documentation.
- They designate the validation method to be used.
- They document, resolve, and/or disposition review comments with designated reviewers and incorporate such into the draft procedure.

- They provide or direct reviewers to references and background information upon which to base their reviews. Although not required to maintain all of the information on file, they are responsible for providing that which is not readily available elsewhere for the history file in Laboratory Technical Information Center.
- They provide legible figures and/or drawings to PA for incorporation, as appropriate.

4.6 Procedure Writers

AS procedure writers are responsible for developing procedures, using applicable writer's guides as described in Section 3.11, "Format and Content of Technical Procedures", and providing specific instructions for task performance under the direction of the appropriate technical authority. They meet the training and qualification requirements established by the Manager, Analytical Services.

4.7 Technical Reviewers

Technical reviewers are responsible for verifying procedures they review in their respective areas of expertise are technically adequate, accurate, and consistent. They meet the training and qualification requirements established by the Manager, Analytical Services.

Technical review comments are normally documented on page two of the PRAF, however, they can be noted on the hard copy or on a separate sheet. The review period, which is normally less than ten working days from receipt of the procedure, is timely. Deviations in review periods are negotiated with the technical authority and PA is notified. As a minimum, procedure reviews conform to the requirements in WHC-CM-3-5, Section 12.7.

- All new procedures, revisions, modifications, and PCAs are reviewed by the assigned technical authority, approval authority, applicable technical reviewers, and PA.
- Incorporation of a PCA is reviewed by the technical authority and approval authority.
- Quality Assurance review is based on the approval designator as defined in WHC-CM-3-5, Section 12.7.
- Safety review is based on the approval designator as defined in WHC-CM-3-5, Section 12.7.
- Procedure changes that have the potential of releasing hazardous material to the
 environment exceeding permitted standards will be reviewed by AS Environmental
 Compliance Officer or designee as defined in WHC-CM-7-5, Environmental
 Compliance.

- Procedure changes concerning radioactive material or hazardous material packaging and transportation are reviewed by Transportation Logistics as defined in WHC-CM-2-14, <u>Hazardous Material Packaging and Shipping</u>.
- Procedure changes used for the measurement of all elements affecting quantities or control of nuclear materials are reviewed by Safeguards Materials Control as defined in WHC-IP-1019, <u>Material Control and Accountability Plan</u>.
- Procedures requiring review for unreviewed safety questions (USQs) are identified
 with a "USQ" suffix and reviewed by those certified to do so. A list of qualified
 USO reviewers is available on the Lab Procedure network directory.

4.7.1 Cross-Disciplinary Review

A procedure can be submitted to additional designated organizations or personnel to ensure it is free of technical errors. The technical authority or approval authority can request this cross-disciplinary review. The reviews are documented on page two of the PRAF and maintained as part of the review record. This review is <u>not</u> mandatory.

4.7.2 Peer Review

A new or revised procedure can be submitted to a peer or peers for independent technical review. Peer reviews are documented on page two of the PRAF and maintained as part of the review record. This review is not mandatory.

4.7.3 User Test (Blue User)

Prior to procedure release, a user test can be performed. The user test can serve as the documented peer review and for qualifying a method. A user test being evaluated as a possible succeeding revision may be used under controlled conditions; however, analytical results are not to be reported until issued as an approved procedure.

User tests are accompanied by a PRAF and appropriate approval signatures. Any active procedure being converted to a blue user is inactivated during the blue user test period.

The user test procedure is controlled by the technical authority. Changes are documented by marking up the hard copy or by making notes in the margin adjacent to the element being changed. Changes are also noted in the shift log and signed by the TA and Approval Authority or Shift Manager or designee.

User test changes may be handled as modifications or revisions, depending on their impact to the actual test. Modifications may be marked on the copy and approved by the technical authority and shift manager or approval authority or designee. Modifications can be approval designator N/A only. Technical changes (revisions) are handled via the PCA process described in this section.

4.8 Verifiers

Verifiers are responsible for the following:

- Reviewing new procedures and procedure changes to verify accuracy, adequacy, and consistency
- Providing comments and recommendations that are consistent with level of expertise and qualification
- Meeting the training and qualification requirements established by the Manager,
 Analytical Services.

4.9 Validators

Validators are responsible for the following:

- Performing validations that are consistent with procedure use in accordance with Section 6.1.2
- Providing comments and recommendations that are consistent with level of expertise and qualification
- Meeting the training and qualification requirements established by the Manager, Analytical Services.

4.10 Procedure Users

Procedure users are responsible for the following:

- Using procedures in accordance with established policy on compliance
- Taking ownership for procedure use and assisting in maintaining those procedures current and accurate.

5.0 REQUIREMENTS

This section is applicable to all elements of the AS laboratory procedure standard for technical procedures. Procedures are developed for anticipated operations, transients, evolutions, surveillances, maintenance, tests, and abnormal or emergency situations. The requirement to develop a procedure, or the extent of detail in a procedure, depends on the complexity of the task, the risk associated with the task, the experience and training of the expected user(s), and the frequency of performance. Laboratory technical procedures include but are not limited to the following:

- Laboratory Analytical Procedures (LAs)
- Laboratory Computer Procedures (LCs)

- Laboratory Essential Materials Procedures (LEs)
- Laboratory Operating Procedures (LOs)
- Laboratory Quality Control Procedures (LQs)
- Laboratory Reference Material Procedures (LRs)
- Laboratory Technology Procedures (LTs)
- Laboratory specific maintenance procedures
- Laboratory specific preventative maintenance procedures
- Laboratory Administrative Procedures (LAPs).

5.1 Training

For the purposes of this section, "training" refers specifically to instructions concerning the laboratory procedures, i.e., training needs created by the change to a procedure or by creation of a new procedure. Whether training is needed and what kind of training is needed is identified by the technical authority on the PRAF. Training options include full training (or retraining), review of procedure before performance, or no training required. Training options must be designated on the PRAF before the procedure is released by Procedures Administration.

Training requirements, methods, and documentation are defined by the Manager, Analytical Services and defined in Section 4.0 of this manual. This section is available in hard copy as part of WHC-CM-5-4, <u>Laboratories Administration</u>, and accessible in electronic format on the Lab Procedures network directory to support training activities.

5.2 Documented Basis

A documented basis is required for all laboratory technical procedures. The basis includes a listing of documents used during procedure development that contains:

- Developmental references (such as vendor material, technical manuals, drawings, etc.), as applicable
- Implementing (requirement) references (such as Westinghouse Hanford Company Level I and II controlled manuals, Occupational Safety and Health Administration, American National Standards Institute/American Society of Mechanical Engineers, U.S. Department of Energy Orders, national standards, Code of Federal Regulations, Safety Analysis Report, Technical Specifications, etc.).

Requirements identified in the documented basis are integrated into the procedure, where applicable and whenever possible. Documents required "in hand" for actual procedure performance are listed in the procedure "Reference" section. For example, the use of EPA methods, such as SW-846, is permitted when the method is directly referred to by an approved technical procedure. Other basis documents, such as developmental references, can be listed in the procedure "Bibliography" section, and included in the history file, if desired.

The documented basis for each procedure change is recorded on the PRAF (see Attachment 2). In this way, the PRAF acts as the authorization for development, revisions, and changes. It also documents reviews and approvals, including disposition of comments. The "Basis for Procedure

Change/New Procedure" block includes what element(s) of the procedure is being changed and why it is being changed, or provides justification for the new procedure. This basis is vital in documenting the evolution of each procedure. As part of the PRAF, it becomes a permanent part of the procedure's history file.

5.3 Procedure Identification

With the exception of maintenance procedures, laboratory technical procedures are assigned a unique identification number based on Appendix B. This identification number appears on the bottom of each page of the procedure. All procedures also have a revision/modification identifier that appears on the bottom of each page. Revisions (except to maintenance procedures) are classified by the first character, a letter, and modifications are identified by the second character, a number. Maintenance procedures are designated 1-0, 2-0, 3-0 for new or revised procedures. Modifications are indicated as 1-A, 1-B, 1-C for maintenance procedure activity. The identifier is separated by a hyphen. Revision identification includes modification of a method as defined by the Hanford Analytical Services Quality Assurance Plan (HASQAP).

Laboratory administrative procedures are identified with the following: the first three characters are the letters "LAP", followed by a consecutive two-digit number, and ending with the three digit user location identifier described in Appendix B, i.e., LAP-45-100. These identifying numbers are assigned by PA.

All procedures related to unreviewed safety questions are identified with a "USQ" suffix, i.e., LO-040-121-USQ. A listing of USQ-related procedures is provided on the Lab Procedure network directory.

5.4 Procedure Use

Goldenrods (performance copies) and procedure change authorizations (PCAs) are maintained at specific controlled user locations, normally in controlled notebooks. Requests for addition or deletion of controlled user locations are addressed in writing or sent electronically via cc:mail to PA. Only PA personnel are allowed to remove goldenrod procedures from controlled user locations.

Goldenrods are released by PA, placed in the controlled user locations, and validated to be the most recent revision. Goldenrods are normally the ONLY valid copies used to perform or record the performance of an activity (some exceptions are noted below). Each is identified as such and as being valid by a release stamp and assigned controlled notebook number on page 1, and by being issued on goldenrod paper.

White copies of procedures are normally used for reference purposes or to record one-time performance of an activity. However, use of white copies is permitted for activities such as filling out data sheets or operational safety limit surveillances, or for performing a procedure requiring signatures for hold points, etc. White copies are available electronically on the Lab Procedure network directory or in hard copy form from Procedures Administration. Before use, white copies must be verified to be the most recent revision and documented as such by printing and signing the "approved for use" block in the lower right hand corner with user name and date. Verification of the most recent revision is accomplished by comparing the revision or modification with the goldenrod

located in the laboratory where the activity is taking place or contacting PA. Performance copies of PCA'd procedures are obtained from PA.

6.0 PROCEDURE REVIEW, APPROVAL, AND CHANGE CONTROL

6.1 Review and Approval

New procedures and procedure changes are reviewed and approved on a PRAF in accordance with the approval designator assigned by the technical authority in accordance with WHC-CM-3-5, Section 12.7. The approval designator of the PRAF indicates the impact of the change being approved, not that of the original procedure (unless the procedure is new). The approval designator of the procedure and the PRAF are not always the same.

Minimum review and approval requirements for new or revised procedures, modifications, and PCAs include the technical authority, approval authority, those required by the approval designator, and PA. Reviewer comments are documented on page 2 of the PRAF or by annotating and initialing the hard copy. The PRAF may be signed if desired, or signature may be obtained after comment resolution and incorporation.

Procedures requiring USQ review are identified in Section 3.13 of this manual, "Unreviewed Safety Questions Program". They are identified by the USQ suffix and contained in a "LO-USQ" directory in the Lab Procedure network directory.

The PA prepares a PRAF and routes the PRAF and new or revised procedure to the designated reviewers for approval. Each reviewer summarizes comments on page 2 of the PRAF or annotates and initials the hard copy, signs the PRAF (if desired, or after comment resolution and incorporation), and returns the PRAF and reviewed procedure to PA in a timely manner (normally 10 working days), unless prior notification to PA is made.

Cross-disciplinary reviews are performed whenever any of the following conditions apply.

- The response of a system under the direct control of another group is altered and notification of the affected group is required.
- The steps in a procedure may affect the use or operation of equipment under the control of another group.
- Cases where expertise in specific disciplines or specialized training are needed beyond that of the primary reviewer(s) to ensure a complete technical review of the procedure.

6.1.1 Verification

Procedure verification is performed by the Technical Authority on new and revised procedures. The following statements explain why verification is documented by review signature on the PRAF.

- To verify information contained within the procedure is accurate and complete.
- To verify the procedure is free of errors, easy to understand, and meets the guidelines of Section 3.11 of this manual for content and format.
- To verify applicable safety requirements or limits are identified and satisfied. The reviewer checks for omissions of Technical Specification or Operational Safety Requirements provisions that may not be identified in the procedure.
- To verify the procedure does not contain steps that could potentially lead to Technical Specification or Operational Safety Requirements violations, expose personnel or the environment to hazardous conditions, or cause equipment damage.
- To verify the procedure can be accomplished in the sequence written.
- To verify the procedure provides for easy interaction between groups, and efficient use of resources.
- To verify references specified in the procedure are applicable to the procedure being performed.

6.1.2 Validation

Procedure validation is performed on new procedures and procedure revisions.

Procedure validation method is determined by the Technical Authority and performed by personnel responsible for normal performance of the procedure by any of the methods described below.

Validation is documented by signature on the PRAF and retained in the procedure history file. The validation steps contained in the checklist in Attachment 5 are addressed or the checklist itself may be used and included in the history file. The appropriate validation method is determined by the Technical Authority based on the scope, hazard risk, and application of each procedure.

The "walk-through" method is preferred for validation. Alternate methods may be used when a walk-through is not practical. The following explain the walkthrough method and some alternate methods.

- Walk-through method. A method in which the intended users take the procedure to the location where the task is to be done and, without actually performing the task, ensure that each step is correct and readily usable as written. Where available, a simulator may be used for this method.
- Reference method. A method where an analytical review that does not simulate actual operation, but validates the procedure through document reviews. This method may be used for procedures developed from a previously performed

procedure (such as a work package, test procedure or vendor technical manual). To use this method, the procedure must have been performed using the parent document and must contain the same instructions.

The procedure is then validated based on the fact that the instructions were performed successfully via another document.

- <u>Simulation Method</u>. A method whereby personnel who would normally perform the procedure do so on simulators or mock-ups of the equipment.
- <u>Table Top Method</u>. A method whereby personnel explain and/or discuss procedure action steps. Appropriate drawings and references are used.

6.1.3 Comment Disposition

All organizations and personnel that formally request or are required to review a procedure are provided an opportunity for such review. Valid technical comments received during such reviews are resolved in a timely manner between the technical authority and the reviewers, and disposition is documented on page two of the PRAF. If review is not completed within 20 working days, the approval authority can issue the procedure without reviewer approval, unless an extension of time to complete the review is negotiated.

6.1.4 Final Administrative Review

Before release for use, a final administrative review is performed by Procedures Administration to ensure the new procedure or procedure change is accurate and consistent with the laboratory procedure function. The following are included in the review verification.

- The development and review process is completed in accordance with this section defining the laboratory procedure function.
- The procedure meets the guidelines for format and content.
- References specified in the procedure are current and applicable to the procedure being performed.
- Reviews are performed by all groups identified to be affected by the procedure and by organizations specified in WHC-CM-3-5, Section 12.7.
- Technical comments received during the review process are resolved and dispositioned, and incorporated when applicable.

6.1.5 Approval and Telecon Approval

The number of approvals is minimized to encourage procedure ownership. Each procedure is approved on a PRAF in accordance with WHC-CM-3-5, Section 12.7, and other Westinghouse

Hanford Company approval requirements (such as Packaging and Shipping, Radiological Control, etc.).

When a change to an approved laboratory technical procedure is identified as urgent, the change is initiated in accordance with this laboratory procedure function. Reviews and approvals may be obtained via telephone (telecon) or sent electronically via cc:mail. The following criteria apply to all telecon changes.

- The person called to perform the review and grant an approval accepts full
 responsibility for ensuring that the review performed is adequate for the approval
 granted.
- The person calling for approval documents the approval on the PRAF or procedure by printing the date and the name of the person called near the change made and approved. The caller signs and prints their name near the name of the person giving approval and indicates the approval was "per telecon."

6.2 Change Control

Procedure changes are necessary to ensure procedures reflect current practices, equipment changes, and new requirements. When need for a change to an approved procedure is identified, the change is initiated and processed in accordance with this section. The review and approval process for each procedure change is documented on a PRAF.

Changes to laboratory technical procedures are considered either modifications or revisions. Any technical authority, approval authority, or procedure user can initiate a procedure change.

- 1. The initiator provides a copy of the proposed changes, clearly written or highlighted on hard copy to Procedures Administration. Electronic copies of changes are not acceptable, unless specifically approved by PA.
- 2. The TA determines if the change is correct and should be incorporated into the procedure. Discuss with initiator.
- 3. The TA determines if the change is a modification or revision.
- 4. The TA informs other users of the procedure that a change is in process and determines what effect a change will have on their use of the procedure.

After changes to a procedure are received and incorporated, PA returns the changed procedure to the TA. If the initiator and technical authority are not the same individual, the approval authority for the procedure is contacted for review and technical authority review. The procedure is then routed to the assigned technical authority for review and approval.

6.2.1 Modifications

Modifications are reviewed and approved on a PRAF and in accordance with this section.

Modifications are limited to:

- Alterations that do not change the procedure's intent, quality, safety, or process
- Format changes that do NOT alter the technical content of the procedure
- Correction of grammatical, typographical, or spelling errors that do NOT affect:
 - numbers (other than page, step, table, figure title numbers, or <u>obvious</u> typographical errors)
 - units of measure, including updates to metric configuration
 - nameplate information/data
 - acceptance QC criteria, detection limit, accuracy, and precision
- Update of position or organizational names or titles, if the change does not alter responsibilities with regard to AS laboratory procedure functions
- Update of references, unless there has been a change in the reference that affects the technical content of the procedure
- Pagination, table, or figure title number changes.

6.2.2 Revisions

Revisions include any change that does not meet the criteria of a modification, including modification of a regulatory method (see HASQAP, Sections 8.4, 8.5, and 8.6). Typical revisions include changing the technical content of a procedure, altering results, or affecting the approval designation. A technical change is also initiated when a procedure is determined to be difficult to follow. Normally, no more than five modifications are incorporated before a procedure revision is required, however, exceptions do exist, based on extent of changes and procedure flow. A technical change to a laboratory technical procedure is reviewed and approved on a PRAF. Technical changes made and incorporated into the procedure conform to criteria set forth in this laboratory procedure function.

Any outstanding temporary change (PCA) that exists against a procedure in revision will be incorporated into the new revision or canceled upon issuance of a new revision. A new PCA will be required if needed.

6.2.3 Incorporation of Changes

Approved changes are incorporated in accordance with this section. Pen and ink changes are not allowed. The use of tape or obliterating agents in a procedure is also not allowed. Redlines and strikeouts are used with all changes during the review process to quickly identify what procedure content has been changed. Before release of modifications, strikeouts are removed and redlines

("change marks") are moved to the left margin. For modifications, each changed portion of the procedure is identified by a single vertical line in the left margin corresponding to the number of lines changed. The change marks indicate changes in the current modification only. Change marks from previous versions are removed.

6.2.4 Temporary Changes

Temporary changes are issued via PCA to immediately implement a technical change or permit a temporary departure from an existing procedure for a 90-day period of time or duration of an event. Only one PCA is allowed on any one procedure at any given time. Immediate temporary departure for certain instances, such as correcting safety, operational difficulties or technical improvements, is authorized by the issuance of a PCA (see Attachment 1). Procedure Change Authorizations designate the period of time or duration of the event for which they are valid and are subject to a 90-day review to ensure final cancellation, incorporation into an existing procedure, or 30-day extension. Extensions are obtained by contacting PA, who will revise and initial the date on the master, release and issue new copies, and update ZDOX to reflect the extended date.

Procedure Change Authorizations are issued on pink paper for immediate identification and inserted into the goldenrod copies. They are considered controlled documents and tracked by PA. Laboratory technical procedures are allowed only one PCA issued against them at any one time.

Procedure Change Authorizations are required to be reviewed and approved as determined by the approval designator of the procedure and PCA changes. The following requirements also apply.

- A PCA number (SL-XXXXX) is obtained from PA, who maintains a logbook and tracks the activity on ZDOX.
- The initiator (normally technical authority) submits the PCA to PA at the time of the change or on the next business day.
- The PCA number appears on each page of the procedure that is changed by the PCA, and on each PCA continuation page.
- PCA format can be any of the following:
 - PCA continuation pages. A new PCA continuation page is used for each page of the procedure that is changed. Changes on multiple pages of a procedure cannot be combined onto one PCA continuation sheet.
 - Annotated pages. If PCA changes allow, a marked-up copy of the procedure is attached to the PCA.
 - Annotated document. Copy printed off the Lab Procedures Drive and redlined.
- All required approvals are obtained or the PCA cannot be released or issued.

If a deviation from a procedure is required and a PCA number cannot be obtained from PA in a reasonable period of time (such as during a weekend), documentation of the deviation is made on a PCA form, approved in accordance with the approval designator, and submitted to PA on the next business day for processing.

If a PCA is written that applies only for a specific time period or for specific activities, that PCA may be canceled upon completion of the work activity or time period. Cancellation of a PCA is accomplished by obtaining the file copy of the PCA from PA and acquiring the required approvals in the "Work Completion/Cancellation" block.

6.3 Inactivations and Voids

When AS procedures are no longer required in AS facilities or by AS organizations or personnel, they are removed from active status. The following methods are used to remove an active procedure to an inactive (hold) or void (canceled) status.

- 1. Technical authorities and/or approval authorities notify PA in writing that a procedure needs to be removed from active status. The notification to be inactivated or voided, and the effective date for change of status is included. Normally, a PRAF is used for this notification.
- 2. Procedures Administration enters the inactive or void notification into the tracking system, removes the procedure from the controlled notebook, stamps the original procedure "Inactive" or "Void," and files the notification in the procedure history file in the Laboratory Technical Information Center.

6.4 Reactivations

Reactivation of an inactive or void procedure is initiated and documented on a PRAF. Normally, reactivations result from a renewed need for a procedure or to restore a procedure that has passed its periodic review. An inactive document can be reactivated and placed back into use without a review if the periodic review date has not passed. However, if the periodic review date has passed, the procedure requires a full review by the technical authority, approval authority, and those required by the approval designator before reissue.

6.5 Periodic Review

To ensure the technical accuracy and adequacy of procedures, the following review cycle has been established for laboratory technical procedures, based on the associated approval designator:

- Any Safety (S) approval designator 2 years
- Any Environmental (E) or Quality (Q) approval designator 3 years
- Any Not Applicable (NA) approval designator 5 years.

This review cycle meets criteria for procedure, type of equipment or system affected, vulnerability, safety implications, and frequency of procedure use for determining the review interval. Manufacturer's documents are considered, as appropriate, during this review. This meets the requirements of WHC-SP-0708, Westinghouse Hanford Company Conduct of Operations Manual, Chapter 16, "Operations Procedures" and WHC-CM-3-5, Section 12.5.

Laboratory technical procedures are tracked by Procedures Administration to determine when periodic reviews are required. Technical authorities are notified at two-month, one-month, two-week, and one-day intervals to assure periodic review is completed as scheduled. The periodic review is documented on a PRAF and submitted to Procedure Administration for laboratory procedure processing and entry into the database tracking system.

Any procedure that passes its required periodic review date is removed from controlled notebooks and placed in inactive status by PA until formal review is acquired or notice of reactivation is submitted by the technical and approval authorities.

Periodic reviews are based on the time interval from initial release of the procedure, with the clock being reset for any complete revision of the procedure. The new date of periodic review will be established from the date of release.

6.6 Procedure Use Requirements

Laboratory technical procedures are readily available at controlled user locations throughout AS facilities. Goldenrods are clearly identified by the release stamp and assigned controlled notebook number on page one, and their color (issued on goldenrod paper). This assures the user that the procedures are valid, controlled to laboratory procedure functional requirements, and the most current revision available.

Status of any laboratory technical procedure can be confirmed by consulting the Analytical Services Laboratory Procedure index available on Soft Reporting or by contacting Procedures Administration prior to use.

Analytical Services laboratory technical procedure activities are conducted in accordance with applicable documents reflecting facility design bases. The requirements for use of procedures are clearly defined and understood by all procedure users. If procedure changes are required, a modification or revision is initiated.

6.7 Records

6.7.1 Indexes and Files

The following indexes and files are maintained by Procedures Administration.

• A master database of AS laboratory technical procedures is maintained current via ZDOX Laboratory Procedure Tracking System.

- A master database of AS maintenance procedures is maintained current via MAINTRAK Laboratory Procedure Tracking System.
- A master index of AS laboratory technical procedures is maintained current via ZDOX to Analytical Service Laboratory Procedures available on Soft Reporting.
- A master file is maintained in Laboratory Technical Information Center for each procedure identified by the master index.
- The master file contains a controlled master of the most current version of the procedure.
- The master file is kept current and maintained as a controlled source for generating goldenrods.
- The electronic (computer based) procedure master file also has a backup.
- A history file is established and maintained in Laboratory Technical Information Center for each procedure defined by the master index. The history file contains a record of all changes to each procedure, including comments received during the review cycle and their disposition. For example, copies of signed PRAFs are kept here. The file is available in hard-copy or via other archival media.

6.7.2 Records

Any records generated as a result of employing laboratory technical procedures will be processed through data package or work control activities in accordance with this manual and dispositioned in accordance with applicable sections of WHC-CM-3-5, <u>Document Control and Records Management Manual</u> and applicable Records Inventory and Disposition Schedules.

7.0 DESIGNATED REVIEWERS

[Designated Reviewing Organizations	<u>MSIN</u>
	HAS Records (Champion)	T6-03
1	222-S Procedures Conduct of Operations Champion	T6-20
]	Environmental Compliance	T6-12
1	Operations Support	T6-51
1	Quality Systems	T6-04
1	WSCF	S3-28
1	222-S Operations	T6-12

8.0 REFERENCES

DOE-RL-94-55, Hanford Analytical Services Quality Assurance Plan.

DOE-STD-1029-92, "Writer's Guide for Technical Procedures."

HSRCM-1, Rev. 2, <u>Hanford Site Radiological Control Manual</u>, Pacific Northwest Laboratories, Richland, Washington.

LAP-106-100, <u>Waste Stream Fact Sheet Development and Issuance (Predesignation of Waste)</u>, Hanford Analytical Services, Richland, Washington.

WHC-CM-1-8, Work Management.

WHC-CM-2-14, Hazardous Material Packaging and Shipping Manual.

WHC-CM-3-5, Document Control and Records Management Manual.

WHC-CM-3-6, Uniform Publications System.

WHC-CM-4-3, Industrial Safety Manual.

WHC-CM-4-29, Nuclear Criticality Safety Manual.

WHC-CM-4-40, Industrial Hygiene Manual.

WHC-CM-4-46, Nonreactor Facility Safety Analysis Manual.

WHC-CM-7-5, Environmental Compliance Manual.

WHC-SP-0708, Westinghouse Hanford Company Conduct of Operations Manual.

Carlson, D. D., 1995, <u>Laboratory Reagents</u>, WHC-SD-CP-LB-028, Westinghouse Hanford Company, Richland, Washington.

Serier, M. N., 1994, Material Control and Accountability Plan, WHC-IP-1019, Westinghouse Hanford Company, Richland, Washington.

ATTACHMENT 1

EXAMPLE OF AN ANALYTICAL SERVICES . PROCEDURE CHANGE AUTHORIZATION

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Attachment 1. Example of an Analytical Services Procedure Change Authorization (Sheet 1 of 2)

Analytical Services	Approve Designator	PCA No.	
Procedure Change Authorization		SL-	Page 1 of
Procedure No.	Rel/Mod	PCA Effective Date	
Title :		PCA Expiration Date	
Easitity		PCA Type	on Thest Attached
Change Requisited By		T T STATE OF THE S	I Pages Attaches I Cobustert Attached
(Harriel)		Golderwod topostoria (Ferformanos	Coptest:
(Title(Organization)) Approval	Phone	Reaviti für Chänge	
Approvas			
(Technical Authority)	(Date)		
(Operations)	(Date)	Traising Required	
(Safety)	{Date}	[] Full retraining	-
(Environmental)	(Date)	() None requires	
(QA)	(Date)	Sometimenting this change wall reco	equature compatible?
(Other)	(Date)	[] Yes (Described on P	66.23
(Other)	(Date)	7 7 170 Pag Apply 5 400 10 27 10 20 10 20 20 20 20 20 20 20 20 20 20 20 20 20	
Final Approval		Work Completion/Cancellation Due to [] Work Completed (p [] Other — Explain:	for to expiration)
(Approval Authority)	(Date)		-
Distribution:		SIGNATURES	
Tachnical Authority Approval Authority LTS Support K. M. Higley	T6-51	Technical Authority	Date
Other K. M. HIGIEY Other	10-01	Approval Authority	Date

Attachment 1. Example of an Analytical Services Procedure Change Authorization (Sheet 2 of 2)

Description of persons region to principle (to history and proportion compatible of appropriate
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and appropriate the Control of the C
and appropriate the Control of the C

ATTACHMENT 2 EXAMPLE OF A PROCEDURE REVIEW AND APPROVAL FORM

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Attachment 2. Example of a Procedure Review and Approval Form (Sheet 1 of 2)

ANALYTICAL SERVICES Procedure Review and Approval Form Page 1 of			
Prosedure Number Current	Approval Designator	Technical Authority / Approval Authority	
,	fer Change		2000
and the control of th		Charge Requested By	Signature/Date
			diconstantists.
		94	***
		Goldenroe Locations (performance copies):	
Keywords (9)		Goldenios Locations (garjormanos copies)	
I New Procedure — Veldetlon algorithm required below	Revitiod ReviMos	PERIODIC REVIEW OF LABORATORY	PROCEDURE
Validation's gnature regulared balos		Procedure Review Date	
[] RevisionValidation elimatuse required below		Date Due to Procedures Administration	,
Madification	kanadah patranika	•	
[] Modification —No validation required		This laboratory procedure required and found to be	has been reviewed as satisfactory for continued
[:] PEANOT	porated	safe operation.	
[] (Jac Teet ("Blue-(Jeer")		Change Required	
[] (Dear Taus 20-stey Edwindle			
[] Inscrivates [] Yell .	Reactivete	(Technical Authority)	(Date)
Training Sequiped Training/Negualification			
Havjawi kefora performing		(Approval Authority)	(Date)
Basis for Propedure Change/New Propedure		propiestation this charge will require constraint to propiestation and propositions admirable to the propiest of the propiest	
	i i a S an aga da parti	[] yesterrayer [] We	
	B		
		re Review Liblack ink only)	
With Add'i NOT ACCEPTAL As is Changes (see page 2)			
(soe page 2)			
	(Technical Authority Signati	re) (Print Name)	(Date)
	(Validator Signature)	walk-through [] reference [] simulation [] t	able-top (Date)
	(Operations Signature)	(Print Name)	(Date)
	(Safety Signature)	(Print Name)	(Date)
	(Environmental Signature)	(Print Name)	(Date)
		(Print Name)	(Date)
	(QA Signature)		(Date)
lri ri ri	(Other Signature)	(Org.) (Print Name)	
	(Other Signature)	(Org.) (Print Name)	(Date)
' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '	(Other Signature)	(Org.) (Print Name)	(Date)

Attachment 2. Example of a Procedure Review and Approval Form (Sheet 2 of 2)

Procedure Malmbery Current Revision				
Description of operator actions require	ed to make equipment ar	nd procedures compatible, N applicabl	a.	
	·			
		Review and Comment		
•	Signature	Title/Org	Data	
		Review and Comment		
				Ì
,				
	Signature	Title/Org	Date	
APPROVAL AUTHORITY			t1	ALL OBJECTIONS RESOLVED UNRESOLVED ISSUÉ EXISTS
(Signature)		(Date)		UNRESOLVED ISSUE EXISTS
(Signature)	For Proc	edures Administration (se Only	
PROCEDURES ADMINISTRATION (IN	view for WHC-CM-5-4 o	ompliance, insert release date, move	to network, distribute, fil	• master) Distribution initials
(Signature)				(Data) "
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				

ATTACHMENT 3

EXAMPLE OF A MAINTENANCE PROCEDURE REVIEW AND APPROVAL FORM

Attachment 3. Example of a Maintenance Procedure Review and Approval Form (Sheet 1 of 2)

ANALYTICAL SERVICES			
		eview and Approval Form Page _	of
Procedure Number:	Approved Designator for Change	Managet/Approval Authority Tactinical Authority	
		Oto LAB ENGINEERING Validation (Cappillo)	
Keyvords (3)		Maintenance Engineer	
[] Haw Procedure 7 To 1888 Sec. 28		PERIODIC REVIEW OF LABORATORY PROCEDURE	
New/	Chg Rey/Chg	Procedure Review Date	 .
T 1 Favision		Date Due to Procedures Administration	
Validation algorithm required below Field Charge No validation required		This laboratory procedure has been revi required and found to be satisfactory to safe operation.	iewed as er continued
[] Klastväte		Change Required	
[] Vold		(Technical Authority)	(Date)
[] Rearrivers		(Manager/Approval Authority)	(Date)
Bade for Propedure Charger/law Propedure		TROSA Related? (1 to 13 Ver Bed.) Discreption regalise CBRs of ICS Discreption (Provising) L.J. Ken	ANGE INA
		Participation Control Services	a no company of the
(Requested By/Date)	(Ore)	Start (affer procedure reque):	
ACCEPTABLE NOT ACCEPTABLE As is With Add'! (see revelse) Changes [] [] []		e Review 3 algn in black ink only)	
	(Technical Authority)		(Date)
	(Validator) [] w	alk-through [] reference [] simulation [] table-top	(Date)
	(Operations)		(Date)
	(Safety)		(Dete)
	(Environmental)		(Date)
	(QA)		(Date)
	(Other)	(Org.)	(Date)
	(Other)	(Org.)	(Date)
	(Other)	{Org.}	(Date)

Attachment 3. Example of a Maintenance Procedure Review and Approval Form (Sheet 2 of 2)

Procedure Humber / Rev/Cing				
	R	eview and Commer	nt	
				,
	Signature	Title/Org	Date	
	R	eview and Commer	nt .	
•				
•				
	Signature	Title/Org	Date	·
APPROVAL AUTHORITY				() ALL OBJECTIONS RESOLVED () UNRESOLVED ISSUE EXISTS
(Signature)		(Data)		[] UNRESOLVED ISSUE EXISTS
	For Proced	lures Administration	Use Only	
				1
	•			
PROCEEDINGS ADMINISTRATION (random for MACC PARS 4	Sance investment date me	ve to natural, native	ork control, file master) Dist. Initials
FROCEDURES ADMINISTRATION (I	dutes to itilo-ent-ni terrere	manue, moer, (seres cors, fic	itaetenise itanii 4 da	
(Signature)			*****	(Date)

PRAFMAIN.FRM 08/22/95

ATTACHMENT 4

EXAMPLE OF A 222-S LABORATORY WASTE STREAM FACT SHEET

January 15, 1996 Attachment 4-3 of 4

Attachment 4. Example of a 222-S Laboratory Waste Stream Fact Sheet (Sheet 1 of 1)

222-S LABORATORY WASTE STREAM FACT SHEET

Proced	lure	Number:
Waste	Desc	ription:
Dispos	al:	•

Radionuclide:

Room/Hood number(s):

Reagents and Standards used:

WASTE GENERATED	APPROXIMATE VOLUME	APPROXIMATE WEIGHT %	WASTE CODE

Name:	Name:
Signature:	Signature:
Date:	Date:
Title/Org:	Title/Org:

ATTACHMENT 5 PROCEDURE REVIEW CHECKLIST

This checklist is designed to assist personnel in performing a procedure review. Validation methods are defined in paragraph 6.1.2. Technical comments, if any, are recorded on a PRAF or on the back of this checklist, if it is used.

Review Performed		Performed	Validation Method		
	Verification	☐ Validation ☐	Walk Thru Reference Simulat	ion 🗌 Table Top 🔲	
1.	Can the pr	ocedure be performed in	the sequence written?	Yes No N/A	
2.	Can the in	lividual steps be perform	ed?	☐ Yes ☐ No ☐ N/A	
	• Ea		fied the action to be taken (such as open, shut,	Yes No N/A	
	• Li	nitations are expressed q	uantitatively	Yes No No N/A	
	-	uipment and parts are ide nenclature	entified clearly and reflect exact equipment	Yes No N/A	
		ps requiring sign-off are wided	clearly delineated and adequate sign-off space	Yes No No N/A	
		e procedure accurately re ipment	effects the current configuration of the process or	Yes No N/A	
	• Th	e amount and level of inf	formation is adequate	Yes No No N/A	
3.	Can the us	er locate and identify all	equipment referred to in the procedure?	Yes No No N/A	
4.		rocedure provide actions ee (Prerequisites)?	or procedures which must be completed prior to	Yes No No N/A	
	• Pla	nt, system, or equipment	t lineups?	Yes No No N/A	
	• Pr	ecautions to be observed?	•	☐ Yes ☐ No ☐ N/A	
	• Pla	nt, system, or equipment	t limitations?	Yes No No N/A	
	• By	part number or other un	ique nomenclature?	☐ Yes ☐ No ☐ N/A	
5.		er perform the procedure documents?	without obtaining additional information from	Yes No No N/A	
		other documents are need operator to proceed efficient	led, are they referenced clearly enough to allow ciently?	Yes No No N/A	
6.		rocedure include adequat ld points?	e QA, Safety, Environmental,	Yes No No N/A	
7.	Are instruc paragraphs		ncise, identifiable steps as opposed to multi-step	Yes No N/A	
	• In	the correct order to perfe	orm the task?	☐ Yes ☐ No ☐ N/A	
	• Mi	ssing?		☐ Yes ☐ No ☐ N/A	

	 Print	Name	Signature	-	Date
Revie	wed By	7:			
	•	Format editorial requirements		Yes No	□ N/A
	•	Technical guidelines (such as Te	ech Specs)	Yes No	□ N/A
13.	Is the	procedure updated to current guid	elines?	☐ Yes ☐ No	□ N/A
	•	Are actions or referenced proces	dures specified correctly?	☐ Yes ☐ No	□ N/A
	•	Are reporting chains specified co	orrectly?	Yes No	□ N/A
	•	Are correct personnel specified?		☐ Yes ☐ No	□ N/A
12.	If any identif		are must be performed, is that action clearly	Yes No	□ N/A
11.		luded worksheets or data sheets p m necessary calculations?	rovide sufficient space to record data or	Yes No	□ N/A
	•	Are titles descriptive of contents	and use?	Yes No	□ N/A
	•	Are units of scale and measuren	nent useable?	Yes No	□ N/A
	•	Can values be extracted or interp	polated easily?	Yes No	□ N/A
	•	Are they compatible with the pro	ocedure?	Yes No	□ N/A
10.	Are gr	aphs, charts, and tables adequate	for readability and use?	Yes No	□ N/A
9.	Does 1	procedure include signoff spaces for	or independent verifications?	Yes No	□ N/A
8.		otes, cautions, or warnings placed o which they apply?	directly ahead of the	Yes No	□ N/A
	•	Too detailed?		Yes No	□ N/A
	•	Detailed enough to allow perform	mance without interpretation?	☐ Yes ☐ No	□ N/A

APPENDIX A LABORATORY PROCEDURE PROCESS

WHC-CM-5-4,	Laboratories	<u>Administration</u>
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Laboratory Procedures

Appendix A. Laboratory Procedure Process

NOTE:

It is assumed that the Maintenance Engineer accepts Technical Authority responsibilities in regard to maintenance procedures and activities. The term Technical Authority is inclusive of maintenance engineer.

For new procedures:

TECHNICAL AUTHORITY (TA) OR MAINTENANCE ENGINEER (ME)

- 1. Identifies need for a new procedure.
- 2. Prepares a draft procedure in accordance with "Format_and Content Guide for Analytical Services Technical Procedures" (Section 3.11 of this manual). The TA can use the Analytical Services procedure macro for initial electronic draft submission to PA. The procedure macro is available from Procedures Administration.
- 3. Initiates a Procedure Review and Approval Form, available from Procedures Administration (PA) or on the Lab Procedures network directory, and fills in the shaded area per the following.

NOTE:

Procedure Review and Approval Forms (PRAFs) become permanent records. Use care to ensure readability and comprehension. Use black indelible ink. Initiation of the PRAF and providing of the following information may also be done with the assistance of PA upon delivery of the procedure draft and prior to procedure processing. PA must have a completed, signed PRAF requesting a new procedure to proceed with processing.

- a. Determines type of procedure, and assigns a procedure number based on Appendix B, "Laboratory Procedure Numbering."
 PA can assist this activity and will provide the next sequential number. Maintenance procedures are numbered in numerical sequence. The next number may be obtained from PA.
- b. Fill in the Rev/Mod change number for Laboratory Procedures (operational, analytical, etc.) will be A-0, and 0-0 for Maintenance Procedures.
- c. Provides appropriate Approval Designators in accordance with WHC-CM-3-5, Section 12.7.
- d. Provides procedure title.
- e. Provides three keywords associated with the procedure.
- f. Checks "NEW PROCEDURE" box.

- g. Checks appropriate box to indicate any training required for procedure implementation.
- h. Check "yes" or "no" box to indicate whether implementing the procedure will require any operator actions to make lab configuration of equipment and system compatible with the procedure. If "yes", describe action on Page 2 in "Review and Comment" block and obtain Operations signature that required actions are complete.
- i. Provides documented basis for procedure initiation.
- j. Identifies performance copy (goldenrod) locations for procedure distribution.
- k. Provides a desired validation method by checking the validation method under "Procedure Review."
- 1. Enters "RECALL INFORMATION", TS/OSR, and CBRS/JCS information (applicable only to maintenance procedures performed under JCS PM/S or "PM" Recall System).
- m. Designates any additional reviewers as "other" in the "PROCEDURE REVIEW" section.
- n. Prints name and signs "Requested by" on line provided.
- o. Forwards PRAF and procedure draft to PA for processing.
- 4. Reviews PRAF for completeness and correctness of information, and requestor signature. If PRAF is incomplete or incorrect, it is returned to the requestor for action.
- 5. Reviews ZDOX/MAINTRAK tracking system for duplicate procedures, using key words. If the drafted procedure is a duplicate, it is returned to the requestor for an explanation.
- 6. Enters PRAF information into ZDOX/MAINTRAK.
- 7. Arranges into Analytical Services procedure format via macro.
- 8. Types procedure, and arranges for electronic graphics (if needed).
- 9. Tracks on ZDOX/MAINTRAK and routes to Conduct of Operations reviewer (if applicable).

PA

CONDUCT OF OPERATIONS REVIEWER	10.	Reviews procedure and meets with requestor and TA to resolve any issues.
REVIEWER	11.	Routes to technical editor.
TECHNICAL EDITOR	12.	Provides technical editing to ensure completeness and compliance with Analytical Services format and Section 3.11 of this manual. Meets with TA as necessary.
	13.	Tracks and routes to PA.
PA	14.	Tracks and routes formatted draft to TA for review in readiness for full review cycle.
TA	15.	Reviews draft, resolves discrepancies with PA.
	16.	Approves draft, and returns to PA. The TA can sign with changes noted or upon resolution and incorporation of their comments.
PA	17.	Tracks and routes for full review in accordance with approval designator and any additional reviewers identified by TA.
REVIEWER	18.	Verifies procedures they review are technically adequate, accurate, and consistent in their respective areas of expertise.
	19.	Validates per assigned validation method to assure procedure usability, correctness, and compatibility with equipment or system.
	20.	Documents comments on page two of the PRAF or note comments on the review copy, and initials and dates.
	21.	Returns procedure and PRAF to PA, noting comments. Reviewers can sign with changes noted or upon resolution and incorporation of their comments.
PA	22.	Facilitates resolution of any comments between reviewer(s) and TA, and obtains signatures.
	23.	Incorporates changes and prepares final document.
	24.	Performs final administrative review for completeness of PRAF and procedure.
	25.	Tracks and submits to approval authority for review and approval signature.

AA

- 26. Reviews and signs, if approved, resolving any discrepancies with TA, if required.
- 27. Returns to PA.

PΑ

- 28. PA rechecks for completeness and signs as procedure administrator.
- 29. Tracks on ZDOX/MAINTRAK as issued.
- 30. Moves electronic file to Lab Procedures network directory.
- 31. Updates Network Procedure Index (Maintenance only).
- 32. Stamps front page of master copy with release triangle.

NOTE:

Steps 33 through 36 do not need to be completed for Maintenance procedures.

- 33. Notes number of performance copy (goldenrod) locations and makes appropriate number of goldenrod copies.
- 34. Writes goldenrod location numbers in red in release triangle for individual locations.
- 35. Distributes to identified locations.
- 36. Makes one white (information) copy and sends to TA.
- 37. Notifies Work Control and recall system (Maintenance only).
- 38. Files master file in active file.
- 39. Stamps previous copy as superseded and moves to history file.

NOTE:

It is assumed that the Maintenance Engineer accepts Technical Authority responsibilities in regard to maintenance procedures and activities. The term Technical Authority is inclusive of maintenance engineer.

For procedure changes

TECHNICAL AUTHORITY (TA) OR MAINTENANCE ENGINEER (ME)

- 1. Identifies need for a procedure change.
- 2. Prepares hard-copy mark-up of changes. Electronic changes are <u>not</u> accepted by PA.
- 3. Initiates a Procedure Review and Approval Form, available from Procedures Administration (PA) or on the Lab Procedures network directory, and fill in the shaded area per the following.

NOTE:

Procedure Review and Approval Forms (PRAFs) become permanent records. Use care to ensure readability and comprehension. Use black indelible ink. Initiation of the PRAF and providing of the following information may also be done with the assistance of PA upon delivery of the procedure draft and prior to procedure processing. PA must have a completed, signed PRAF requesting the change to proceed with processing.

- a. Changes Rev/Mod designation to reflect letter change for revision and number change for modification. Maintenance procedure designation will reflect number change for revision and letter change for modification.
- b. Provides appropriate Approval Designators in accordance with WHC-CM-3-5, Section 12.7, and the current change. The approval designator reflects the impact of the <u>current change</u> only.
- c. Provides three keywords associated with the procedure.
- d. Checks "REVISION" or "MODIFICATION" (or FIELD CHANGE/EDITORIAL CHANGE if Maintenance procedure) box.
- e. Checks appropriate box to indicate any training required for procedure implementation.
- f. Check "yes" or "no" box to indicate whether implementing the procedure will require any operator actions to make lab configuration of equipment and system compatible with the procedure. If "yes", describe action on Page 2 in "Review and Comment" block and obtain Operations signature that required actions are complete.
- g. Provides documented basis for procedure change.
- h. Confirms performance copy (goldenrod) locations for procedure distribution.
- g. Provides a desired validation method (required for revision only) by checking the validation method under "Procedure Review."
- h. Enters "RECALL INFORMATION", TS/OSR, and CBRS/JCS information (applicable only to maintenance procedures performed under JCS PM/S or "PM" Recall System).
- i. Designates any additional reviewers as "other" in the "PROCEDURE REVIEW" section.

20.

Laboratory Procedures

		j. Prints name and signs "Requested by" on line provided.
		k. Forwards PRAF and hard-copy procedure mark-up to PA for processing.
PA	4.	Reviews PRAF for completeness and correctness of information and "Requested by" signature. If PRAF is incomplete or incorrect, it is returned to requestor for resolution.
	5.	Enters PRAF information into ZDOX/MAINTRAK.
	6.	Ensures procedure format via macro.
	7.	Incorporates changes, using redlines and strikeouts to indicate where changes exist. Arranges for electronic graphics (if needed).
	8.	Tracks on ZDOX/MAINTRAK and routes to Conduct of Operations reviewer (if applicable).
CONDUCT OF OPERATIONS	10.	Reviews procedure and meets with requestor and TA to resolve any issues.
REVIEWER	11.	Routes to technical editor.
TECHNICAL EDITOR	12.	Provides technical editing to assure completeness and compliance with Analytical Services format and Section 3.11 of this manual. Meets with TA as necessary.
	13.	Tracks and routes to PA.
PA	14.	Tracks and routes changed procedure to TA for review in readiness for full review cycle.
TA	15.	Reviews changes and resolves any discrepancies with PA.
	17.	Approves changes, and returns to PA. Reviewers can sign with changes noted or upon resolution and incorporation of their comments.
PA	18.	Tracks and routes for full review in accordance with approval designator and any additional reviewers identified by TA.
REVIEWER	19.	Verifies procedures they review are technically adequate, accurate, and consistent in their respective areas of expertise.

Validates per assigned validation method to assure procedure usability, correctness, and compatibility with equipment or system.

AA

PA

- 21. Documents comments on page two of the PRAF or note comments on the review copy, and initials and dates.
- 22. Returns procedure and PRAF to PA, noting comments. Reviewers can sign with changes noted or upon resolution and incorporation of their comments.
- PA 23. Facilitates resolution of any comments between reviewer(s) and TA, and obtains signatures.
 - 24. Incorporates changes and prepares final document.
 - 25. Performs final administrative review for completeness of PRAF and procedure.
 - 26. Tracks and submits to approval authority for review and approval signature.
 - 27. Reviews and signs, if approved, resolving any discrepancies with TA, if required.
 - 28. Returns to PA.
 - 29. PA rechecks for completeness and signs as procedure administrator.
 - 30. Tracks on ZDOX/MAINTRAK as issued.
 - 31. Moves electronic file to Lab Procedures network directory.
 - 32. Updates Network Procedure Index (Maintenance only).
 - 33. Stamps front page of master copy with release triangle.

NOTE: Steps 34 through 37 do not need to be completed for Maintenance procedures.

- 34. Notes number of performance copy (goldenrod) locations and makes appropriate number of goldenrod copies.
- 35. Writes goldenrod location numbers in red in release triangle for individual locations.
- 36. Distributes to identified locations.
- 37. Makes one white (information) copy and sends to the TA.
- 38. Notifies Work Control and the recall system (Maintenance only).

- 39. Files master file in active file.
- 40. Stamps previous copy as superseded and move to history file.

APPENDIX B LABORATORY NUMBERING PROCEDURE

Appendix B. Laboratory Numbering Procedure

This procedure is used by Procedures Administration and technical authorities to determine the appropriate identification number for procedures.

The Index Category Number (ICN), a part of the total procedure number, is a coded system that identifies the measurement or laboratory activity directed by the method, the technique used, and primary laboratory user. With application of an information-based numbering system, document retrieval time is reduced and addition and removal of procedures can be easily accommodated. This procedure is limited to procedures that are developed and controlled by Analytical Services Procedure Administration.

5.1 General Information

Each laboratory procedure is assigned a unique identification code in the following format, where A is an alphabetic character and N is a number.

Procedure Type (Section 5.2)	AA-		hladdei Awlbii Y	
ICN (Sections 5.3 through 5.6)	ម្ចាស់ស្នាម្ចាស់ ព្រះសង្គម្ចាស់	NNN-		
User Location (Section 5.7)		មាននេះមាននៅក្នុង ប្រើប្រើប្រែក្រុង ប្រែក្រុងក្រុងកំពុំ	N	
Numerical Identifier (Section 5.8)	\$8,5,5,5,1,5,5 2.1. \$1.5.	ija ar il ala ay. Ay il ala ala ay	g vilver Idginii	NN

NOTES:

- The ICN for analytical procedures is based on the first two digits identifying the single or multiple element, ion, compound, isotope or property measured. The third digit of the ICN identifies the measurement technique. Most single element analyses are based on the atomic number of the element of interest. Multiple analyte methods have been assigned numbers that correlate with atomic numbers of elements not normally found in Hanford samples.
- The ICN for operational procedures identifies the type of laboratory support activity covered.

5.2 Procedure Type

5.2.1 Determine the procedure type, using the following listing, and refer to the appropriate Section.

Туре	Laboratory Procedure	See Section
LA	Analytical	5.3
LC	Computer	5.6
LE	Essential Material	5.3
LO	Operating	5.4
LQ	Quality Control	5.3
LR	Reference Material Specification	5.5
LT	Technology	5.3 or 5.4

- 5.3 Analytical, Essential Material, and QC Index Category Numbers
- 5.3.1 Use Table 1 to determine the single element or type of material being analyzed, specified, or controlled by the procedure.

Table 1. Single Element ICN

Element	IC N
Actinium (Ac)	23x
Aluminum (Al)	33x
Americium (Am)	95x
Antimony (Sb)	35x
Argon (Ar)	20x
Arsenic (As)	35x
Astatine (At)	37x
Barium (Ba)	22x
Berkelium (Bk)	97x
Beryllium (Be)	22x
Bismuth (Bi)	35x
Boron (B)	33x

Element	ICN
Gold (Au)	31x
Hafnium (Hf)	24x
Helium (He)	20x
Holium (Ho)	59x
Hydrogen (H)	21x
Indium (In)	33x
Iodine (I)	37x
Iridium (Ir)	28x
Iron (Fe)	28x
Krypton (Kr)	20x
Lanthanum (La)	23x
Lead (Pb)	34x

Element	ICN
Praseodymium (Pr)	59x
Promethium (Pm)	61x
Protactinium (Pa)	91x
Radium (Ra)	22x
Radon (Rn)	20x
Rhenium (Re)	27x
Rhodium (Rh)	28x
Rubidium (Rb)	21x
Ruthenium (Ru)	28x
Samarium (Sm)	59x
Scandium (Sc)	23x
Selenium (Se)	36x

Element	IC N
Bromine (Br)	37x
Cadmium (Cd)	32x
Calcium (Ca)	22x
Californium (Cf)	98x
Carbon (C)	34x
Cerium (Ce)	58x
Cesium (Cs)	21x
Chlorine (Cl)	37x
Chromium (Cr)	26x
Cobalt (Co)	28x
Copper (Cu)	31x
Curium (Cm)	96x
Dysprosium (Dy)	59x
Einsteinium (Es)	*
Erbium (Er)	59x
Europium (Eu)	59x
Fermium (Fm)	*
Fluorine (F)	37x
Francium (Fr)	21x
Gadolinium (Gd)	59x
Gallium (Ga)	33x
Germanium (Ge)	34x

— :	
Element	ICN
Lithium (Li)	21x
Lutetium (Lu)	59x
Magnesium (Mg)	22x
Manganese (Mn)	27x
Mendelevium (Md)	*
Mercury (Hg)	32x
Molybdenum (Mo)	26x
Neodymium (Nd)	59x
Neon (Ne)	20x
Neptunium (Np)	93x
Nickel (Ni)	28x
Niobium (Ni)	25x
Nitrogen (N)	35x
Nobelium (No)	*
Osmium (Os)	28x
Oxygen (O)	36x
Palladium (Pd)	28x
Phosphorus (P)	35x
Platinum (Pt)	28x
Plutonium (Pu)	94x
Polonium (Po)	36x
Potassium (K)	21x
	L

Element	ICN
Element	ICIV
Silicon (Si)	34x
Silver (Ag)	31x
Sodium (Na)	21x
Strontium (Sr)	22x
Sulfur (S)	36x
Tantalum (Ta)	25x
Technetium (Tc)	43x
Tellurium (Te)	36x
Terbium (Tb)	59x
Thallium (TI)	33x
Thorium (Th)	90x
Thulium (Tm)	59x
Tin (Sn)	34x
Titanium (Ti)	24x
Tungsten (W)	26x
Uranium (U)	92x
Vanadium (V)	25x
Xenon (Xe)	20x
Ytterbium (Yb)	59x
Yttrium (Y)	23x
Zinc (Zn)	32x
Zirconium (Zr)	24x

^{*}Not defined.

5.3.2 Use Table 2 for procedures involving multiple determinations or measurements of nonelemental forms.

Table 2. Multielement and Nonelement ICN

ICN	Description
50	Procedures with the capability of determining a number of cations, elements or radioisotopes, with little or no change in equipment or method. Examples are: atomic absorption, emission spectrography, gamma energy analysis, X-ray, ICP.
51	Procedures for measuring physical parameters, such as viscosity, specific gravity, weight, loss on ignition, specific conductance.
52	Procedures for the analysis of organic materials, such as solvents, degradation products, complexants.
53	Procedures with the capability of determining a number of anions. Instrumental examples are the Raman Spectrophotometer and the Ion Chromatograph. (For specific nonelemental anions, see ICN 62, and 64 through 69.)
54	Preparation methods — sample breakdown, evaporation, ion-exchange concentration, alpha, beta, or gamma mounts.
55	Procedures for measuring oxidation/reduction agents, such as permanganate, hydrazine.
56	Procedures for measuring water or moisture in samples or essential materials.
62	Carbonate — CO ₃ -2
63	Ammonium — NH ₄ ⁺
64	Nitrite — NO ₂
65	Nitrate — NO ₃
66	Hydroxide — OH
67	Phosphate — PO ₄ -3
68	Sulfate — SO ₄ -3
69	Cyanide — CN ⁻²

NOTE: Other code groups can be assigned, as necessary, to identify unusual or nonroutine procedures.

NOTE: Quality Control procedures may also use the ICN code 150, which indicates an administrative control procedure.

5.3.3 Determine the third digit of the ICN, using one of the principle methodology or analytical technology codes shown in Table 3.

Table 3. Principle Methodology and Analytical Technology Codes

Code	Keyword(s)	Description
0	Gravimetric	Precipitation, Thermogravimetric Analysis (TGA), density by weight, loss on ignition, and so forth
1	Titrimetric	Acid/base, redox, standard addition, pH electrode (endpoint detection), specific-ion electrodes, volumetric methods
2	Electrochemical	Polarography, coulometry, amperometry, Karl Fischer (water), pH
3	Separations	Liquid/liquid and liquid/solid ion exchange, gas chromatography, liquid chromatography, ion chromatography
4	Evolution Techniques	Combustion, ashing, leaching, pyrohydrolysis, distillation, Differential Scanning Calorimetry (DSC), Differential Thermal Analysis (DTA)
5	Photometric	UV/Vis/IR, fluorescence, emission, Inductively Coupled Plasma (ICP), Atomic Absorption Spectrometry (AAS), Raman
6	Mass Spectrometric	Isotopic ratios, isotopic dilution, sample preparation/support activities
7	Activation	X-Ray Emission/Diffraction/Absorption, neutron/gamma/X-ray activation
8	Nuclear Spectroscopic	Passive alpha, beta, gamma, neutron methods; calorimetry, nondestructive assay (NDA)
9	General	Those procedures whose methodology is not described by the above categories; such as, densitometry, tensiometry, turbidity

- 5.3.4 Go to Sections 5.7 and 5.8 to determine User Location and sequential number assignments.
- 5.4 Laboratory Operating Procedures (LO and LT)
- 5.4.1 Use Table 4 to determine the appropriate ICN.

Table 4. Laboratory Operating (LO) and Technology (LT) ICN.

ICN	Description
001	Process emergency
002	Facility emergency
020	General

ICN	Description
040	Surveillance
060	Ventilation
080	Sampling
085	Safety rules
090	Shipping/receiving/packaging
100	Burial and waste handling
110	Equipment maintenance
120	Chemical makeup
140	Testing of equipment, such as pressure test, calibration
150	Laboratory administrative controls
155	Laboratory procedure preparation
160	Specials (such as hot cell extrusion)
161	Operation of facility equipment
162	Safety equipment/use and maintenance
180	Criticality control/SNM accountability
190	Decontamination of laboratory areas/equipment

- 5.4.2 Go to Sections 5.7 and 5.8 to determine User Location and sequential number assignments.
- 5.5 Reference Material Specifications (LR)
- 5.5.1 The first two letters are always "LR."
- 5.5.2 The ICN is determined as follows.
 - 5.5.2.1 Select the applicable code numbers from Tables 1 and 2.

NOTE: If code 50 (multiple cations) or code 53 (multiple anions) is applicable, the following priority list is used to identify the most important component; and an element is selected from Table 1.

- (1) Special Nuclear Materials (Pu, enriched U, 233U)
- (2) Element with the lowest acceptable uncertainty (greatest precision)

- (3) Element with the highest nuclear activity (most radioactive)
- (4) Element with the highest atomic number (use a standard periodic table).
- 5.5.2.2 Select the applicable methodology or technology from Table 3.
- 5.5.2.3 Go to Sections 5.7 and 5.8 to determine User Location and sequential number assignments.

5.6 Computer Procedures (LC)

5.6.1 The first two digits of the ICN for an LC indicate the individual computer system as shown in Table 5.

Table 5. Computer System Codes

ICN	Description
50	MicroVax systems
60	M-600 systems (PALS, CS/DLS)
65	APPLE Microcomputer systems
68	APPLE MacIntosh Microcomputer systems
70	IBM-PC Microcomputer systems
83	NOVA 830 (SALS)
84	NOVA 840 (SALS)
85	CASS 840 (SALS)

NOTE: Codes may be assigned or deleted as needed.

The third digit of the ICN is used to identify the <u>type</u> of computer operation as shown in Table 6.

Table 6. Type of Computer Application

ICN	Description	
0	Master procedure	
System Procedures		
1	System maintenance, diagnostics, backup, files listing, and so forth	
2	Startup/shutdown procedures	
3	Peripheral equipment operations; tape drives, discs, terminals, line printers, and so forth	

ICN	Description	
4	File maintenance; multi-programmatic or system	
5	Spreadsheet	
	Application Procedures	
8	RUN procedures, including sign-on/sign-off routines	
9	File maintenance; program specific	

NOTE: Codes 6 and 7 are reserved until needed.

5.6.3 Go to Sections 5.7 and 5.8 to determine User Location and sequential number assignments.

5.7 User Location

5.7.1 Select the User Location code from Table 7.

NOTE: The assignment of a particular user location digit <u>does not</u> preclude use of any approved procedure at a different laboratory, provided all applicable safety precautions are

followed.

Table 7. User Location Codes

Code	Description of User Location	
0	Generic laboratory procedure developed for two or more operating locations	
1	222-S Complex, including 222-SA Standards Laboratory	
2	PUREX Analytical Laboratory	
3	PFP Engineering Laboratory, including the nondestructive assay and standards laboratories	
4	Waste Sampling and Characterization Facility (WSCF); may also designate procedures derived from Contract Laboratory Program, Resource Conservation and Recovery Act, SW-846, or other methods ²	

²Any procedure that is derived from other published methods should clearly state the method and version used in the Summary section of the procedure; for example, "This procedure is equivalent to SW-846," or "This procedure implements the technology found in 40 CFR Part 41, Subpart C, Appendix C."

Code	Description of User Location	
5	Special Studies (including Environmental Analytical Laboratory)	
6	Chemical Engineering Laboratory	
7	Engineering and Environmental Demonstration Laboratory	
8	Plutonium Process Support Laboratories	
9	Process Chemistry Laboratories; may also use -1## if a procedure is being tested for eventual transition to a 222-S Analytical Laboratory procedure	

5.8 Numerical Identifier

NOTE: The numerical identifier is the method used to identify individual procedures within the same category at any given user location.

- 5.8.1 Consult the Facility Documentation Master Index to determine the last issued procedure in the category of interest.
- 5.8.2 Consult User Test Procedure and To-be-Issued records to determine if numbers have been assigned to procedures still in preparation.
- 5.8.3 Many categories have been subdivided into two or more subcategories for ease in grouping similar procedures.

NOTE: Category 37x covers procedures for the analysis of fluorine, chlorine, bromine, iodine, and astatine. These have been generally grouped in the following manner.

Chlorine	LA-37x-x01 to LA-37x-x30
Fluorine	LA-37x-x31 to LA-37x-x60
Iodine	LA-37x-x61 to LA-37x-x90
Bromine, astatine	LA-37x-x91 to LA-37x-x99

5.8.4 Based on the guidance given in the previous Steps, determine the numerical identifier, x01 to x99, for the new procedure.

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